

U.S. Application No. 10/069,973  
Response dated February 16, 2005  
Reply to Office Action of December 16, 2004

**REMARKS**

Claims 63-93 are pending in the present application.

**The June 3, 2005 Office Action**

**Restriction Requirement**

In the Office Action mailed June 3, 2005, the Examiner required restriction between the following groups of claims:

Group I, claims 63-65, 69-71, 72-74, drawn to a method for inhibition of apoptosis, or for treating a disease, wherein said disease is a neurodegenerative disease, and wherein the inhibition is at the protein level, comprising contacting a cell with an inhibitor of the activity of adenine nucleotide translocase-1 (ANT-1).

Group II, claims 63-65, 66-68, 72-74, drawn to a method for inhibition of apoptosis, or for treating a disease, wherein said disease is a neurodegenerative disease, and wherein the inhibition is at the nucleic acid level, comprising contacting a cell with an inhibitor of the activity of adenine nucleotide translocase-1 (ANT-1).

Group III, claims 63-65, 66-68, 72-73, 75, drawn to a method for inhibition of apoptosis, or for treating a disease, wherein said disease is a dilated cardiomyopathy, and wherein the inhibition is at the nucleic acid level, comprising contacting a cell with an inhibitor of the activity of adenine nucleotide translocase-1 (ANT 1).

Group IV, claims 63-65, 69-71, 72-73, 75, drawn to a method for inhibition of apoptosis, or for treating a disease wherein said disease is a dilated cardiomyopathy, and wherein the inhibition is at the protein level, comprising contacting a cell with an inhibitor of the activity of adenine nucleotide translocase-1 (ANT-1).

Group V, claims 76-87, drawn to a method for identifying substances that inhibit activity of ANT-1.

Group VI, claims 88-91, drawn to a nucleic acid inhibitor of ANT-1 activity, as disclosed in the specification.

Group VII, claims 88-91, drawn to a polypeptide or peptide inhibitor of ANT-1 activity, as disclosed in the specification.

Group VIII, claims 88-91, drawn to an inhibitor of ANT-1 activity, which are not nucleic acid, nor polypeptide, as disclosed in the specification.

Group IX, Claim 92, drawn to a method for diagnosis of an apoptosis process in a degenerative disease, wherein said disease is a neurodegenerative disease, as disclosed in the specification, comprising detecting the mRNA level of expression of ANT-1.

Group X, Claim 92, drawn to a method for diagnosis of an apoptosis process in a degenerative disease, wherein said disease is a neurodegenerative disease, as disclosed in the specification, comprising detecting the protein level of expression of ANT-1.

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Group XI, Claims 92-93, drawn to a method for diagnosis of an apoptosis process in a degenerative disease, wherein said disease is dilated cardiomyopathy, comprising detecting the mRNA level of expression of ANT-1.

Group XII, Claims 92-93, drawn to a method for diagnosis of an apoptosis process in a degenerative disease, wherein said disease is dilated cardiomyopathy, comprising detecting the protein level of expression of ANT-1.

The Examiner's rationale is set forth in detail at pages 2-4 of the Office Action. Specifically, the Examiner has stated that the inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the art. According to the Examiner, the inventions listed as groups 1-3 do not relate to a single general inventive concept because their same or corresponding technical feature is not a contribution over the prior art.

The Examiner stated that the technical feature of group 1 is inhibition of apoptosis by administration of an inhibitor of ANT-1, which is known in the art. The Examiner stated that Fulda, et al., Cancer Res., 1998, 58(19):4453-60, of record, teaches that apoptosis in neuroblastoma cells is inhibited by bongkreikic acid, which is an inhibitor of ANT-1, as taught by Pei, YZ, et al., 2003, Synthesis-Stuttgart, 11, SI, pages 1717-1721, of record. Thus, in the

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Examiner's opinion, group 1 as a whole lacks novelty or inventive step, and does not make a contribution over the prior art.

In response, Applicants elect Group IV with traverse. Applicants maintain that the corresponding technical feature common to all groups set forth by the Examiner indeed represents a contribution over the prior art. In that regard, Applicants note that the present application contains experimental data showing that apoptosis is induced by the overexpression of ANT-1. On the basis of these findings, it is evident that inhibitors of ANT-1 can inhibit apoptosis and thus also degenerative diseases such as cardiomyopathy.

In the publication by Fulda et al. (1998), apoptosis is induced in neuroblastoma cells by the administration of doxorubicin and betulinic acids. This apoptosis can be inhibited by bongkrelic acid. Applicants point out that Fulda et al. (1998) does not contain any indication that bongkrelic acid is an inhibitor of ANT-1 and that the inhibition of ANT-1 leads to the inhibition of apoptosis, particularly in degenerative diseases like cardiomyopathy.

Further, it is signals which lead to the induction of apoptosis that are decisive in apoptosis. At the time of the priority date, the skilled artisan had no reason to suspect that the apoptosis inducers used by Fulda et al., doxorubicin and betulinic acids, were involved in the development of degenerative diseases, in particularly cardiomyopathy. Consequently, the corresponding technical feature common to all groups set forth by the Examiner indeed represents a contribution over the prior art. Thus, the lack of unity objection set forth by the Examiner is not justified under the PCT Unity of Invention rules governing this application.

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Accordingly, Applicants respectfully request that the Restriction Requirement be withdrawn and all pending claims be examined together.

The Examiner is invited to telephone Applicants' undersigned attorney if it is deemed to expedite allowance of the subject application.

Respectfully submitted,

August 3, 2005

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